AUG 1 3 2002

510(K) SUMMARY
FOR THE
3D NAVIGATION INTERFACE FOR SIREMOBIL ISO-C 3D

Submitted by: K022337

Siemens Medical Solutions USA, Inc.
186 Wood Avenue South
Iselin, NJ 08830

July 16, 2002

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. Contact Person:

Ms. Amy Shaw Hosler
Phone: (732) 321-4830
Fax: (732) 321-4841

2. Device Name and Classification:

Trade Name:	3D Navigation Interface for Siremobil Iso-C 3D
Classification Name:	Accessory to Mobile X-Ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1720
Device Classification:	Class II
Product Code:	90IZL

3. Substantial Equivalence:

The 3D Navigation Interface option for the Siremobil Iso-C 3D is substantially equivalent to the following devices:

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
Siemens Siremobil Iso-C	K973598	11/10/1997
Siemens Siremobil Iso-C 3D	K003266	12/01/2000

4. Device Description:

The 3D-navigation interface is hardware and software interface between the Siremobil Iso-C 3D and commercially available 3rd party navigation systems. The software calculates the navigation matrix required by the external navigation system for the navigation in 3D-image data sets. The matrix is transferred to the navigation system in the DICOM-header of the 3D image data sets.

5. **Intended Use of the Device:**
The 3D Navigation Interface Option does not alter the intended use of the cleared Siremobil Iso-C 3D.

6. **Summary of Technological Characteristics of the Devices Compared to the Predicate:**
The 3D Navigation Interface option does not alter the fundamental scientific technology of the predicate device, Siremobil Iso-C 3D (K003266). The 3D-navigation interface transfers 3D-image data sets acquired with the Siremobil Iso-C 3D and the navigation matrix to an external navigation system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 2002

Ms. Amy Shaw Hosler
Siemens Medical Solutions USA, Inc.
186 Wood Avenue South
ISELIN NJ 08830

Re: K022337
Trade/Device Name: 3d Navigation Interface for Siremobil Iso-C 3D
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobil x-ray system
Regulatory Class: II
Product Code: 90 IZL
Dated: July 16, 2002
Received: July 18, 2002

Dear Ms. Hosler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

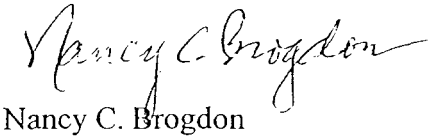
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K022337
Device Name: 3D navigation interface for Siremobil Iso-C 3D

Indications For Use:

The Siremobil Iso-C 3D with the 3D Navigation Interface option is based on Siemens isocentric mobile C-arm, marketed as Siremobil Iso-C. The 3D imaging option of the Siremobil Iso-C 3D contains hardware for the motorized movement of the orbital axis, a 3D workstation and a software package for volume reconstruction from two-dimensional images, 3D post-processing and visualization.

The Siremobil Iso-C 3D with the 3D Navigation Interface option is intended to be used whenever the surgeon benefits from intraoperatively generated 3D information of high contrast objects and anatomical structures (e.g. bones and joints). The Siremobil Iso-C 3D with the 3D Navigation Interface option is designed as a 3D imaging device for conditions such as complex bone or joint fractures of the upper and lower extremities (including knee, foot, elbow, hand), and the spine.

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

David G. Legerwood

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022337

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)